

March 1, 2006 **United States**

Department of Agriculture

CENTER FOR VETERINARY BIOLOGICS NOTICE NO. 06-05

Animal and Plant Health Inspection Service

Issuance of Conditional Licenses for Avian Influenza Vaccine, Killed Subject:

Virus – Subtypes H5N2, H5N9, H7N2, H7N3

Veterinary Services

Center for Veterinary

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Biologics

To:

Biologics Licensees, Permittees, and Applicants

Veterinary Services Management Team Directors, Center for Veterinary Biologics

Area Veterinarians in Charge, VS

State Veterinarians

The Animal and Plant Health Inspection Service (APHIS) has issued conditional United States Veterinary Biological Product Licenses to Wyeth, Establishment No. 112, Fort Dodge, Iowa, for the manufacture and distribution of:

Avian Influenza Vaccine, H5N2 Subtype, Killed Virus Avian Influenza Vaccine, H5N9 Subtype, Killed Virus Avian Influenza Vaccine, H7N2 Subtype, Killed Virus Avian Influenza Vaccine, H7N3 Subtype, Killed Virus

A veterinary biological product regulated under the Virus-Serum-Toxin Act must be shown to be pure, safe, potent, and efficacious before a veterinary biological product license may be issued. The regulations in 9 CFR Part 102 regarding the licensing of biological products provide that a conditional veterinary biological product license may be issued to meet an emergency situation, limited market, local situation, or other special circumstances. There is a need to have products available to enable rapid and effective response to the possible occurrence of avian influenza in the domestic chicken flock.

These conditional licenses were issued following the acceptance of data demonstrating safety and an expectation of efficacy. The products are restricted to use only in chickens, and only under the supervision and control of USDA, APHIS, Veterinary Services.

/s/ Byron E. Rippke for

Richard E. Hill, Jr. Director Center for Veterinary Biologics



APHIS Safeguarding American Agriculture